IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to:	Case No. 17-md-2804
Track One Cases	Hon. Dan Aaron Polster

TEVA DEFENDANTS' AND ACTAVIS GENERIC DEFENDANTS'
OMNIBUS MOTION IN LIMINE

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Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Cephalon, Inc. ("Cephalon"), (collectively, the "Teva Defendants") and the Actavis Generic Defendants[1] (collectively, "Moving Defendants") seek to preclude Cuyahoga and Summit Counties (the "Counties" or "Plaintiffs") from referring to or otherwise offering at trial, information or evidence in any form (whether through direct or cross-examination, expert testimony, or through exhibits of any type) and from presenting to the jury in any manner (whether in opening statements, questions to witnesses or experts, objections, closing arguments, or otherwise) the evidence set forth below.[2]

A. The Court Should Exclude Reference To The Cephalon Misdemeanor Plea (TAD-1).

Throughout this case, Plaintiffs have made repeated references to Cephalon's 2008 misdemeanor plea (the "Plea"). *See, e.g.*, Third Am. Compl. ("Summit TAC") ¶ 787, ECF No. 1465; Pls.' Opp'n. Teva & Actavis Def.'s Mot. Summ. J., ("Opp."), at 6, 10, ECF No. 2188. In 2008, Cephalon pleaded guilty to a single misdemeanor count of off-label promotion of three medicines (only one of which was an opioid) limited to an eight-month period in 2001. Ex. 1, ¶ 6(A). The Plea contained ***no*** admission that Cephalon made any misrepresentation regarding opioids, or overstated their benefits or understated their risks. *Id.*

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[1] The Actavis Generic Defendants include: Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida. Teva Ltd. is an Israeli company that is not subject to personal jurisdiction for the reasons stated in its motion to dismiss for lack of personal jurisdiction. It is specially appearing to join this submission; thus, it does not waive and continues to contest personal jurisdiction and to preserve its pending personal jurisdiction challenge.

[2] The Teva and Actavis Defendants have joined the Omnibus Memorandum Of Law In Support Of All Bellwether Track 1 Trial Defendants' Motions In Limine ("Joint Brief").

The Plea is irrelevant to any fact of consequence in this litigation. Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."). A false statement is not an element of the misdemeanor offense to which Cephalon pleaded guilty, nor did Cephalon admit to making any false representations or omissions. The Plea certainly does not prove that Cephalon's marketing caused any allegedly adverse events in or harm to the Counties. Nor does it address any aspect of Cephalon's suspicious order monitoring program or its compliance with obligations under the Controlled Substances Act. It is simply not relevant to the issues to be tried in this case.

Instead, the Plea is precisely the type of character evidence that Rule 404(b) excludes. Rule 404 makes clear that "[e]vidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid 404(a)(1). Thus, Rule 404 bars the use of the evidence of the Plea to portray Cephalon as a bad actor who broke the law and, thus, acted in conformity with that bad character in connection with opioid marketing activities in the Counties. Such evidence of a prior "crime, wrong, or other act" may be admissible only if the party proffering the evidence can show it will be used for some reason ***other than*** showing action in conformity with the character of a party. *Simmons v. Napier*, 626 F. App'x 129, 135 (6th Cir. 2015); *see Crabbs v. Pitts*, No. 2:16-CV-0387, 2018 WL 5262397, at *10 (S.D. Ohio Oct. 23, 2018) (applying rule to exclude evidence of prior discipline because the evidence was not "probative of a material issue other than character."). There is no such reason here. Indeed, Plaintiffs have identified no reason for introducing the Plea other than to paint Cephalon as a criminal. As a result, Rule 404 precludes Plaintiffs from making any reference to the Plea at trial.

Even if the Plea had some legitimate relevance to Plaintiffs' claims, which it does not, that would be far outweighed by the risks of unfair prejudice under Fed. R. Evid. 403. *See Ragsdale*

v. Sidoti, No. 5:12 CV 2484, 2015 WL 10986351, at *3 (N.D. Ohio July 7, 2015) ("Before the court may admit 404(b) evidence, it must . . . apply Rule 403 balancing to determine whether the probative value of the evidence is substantially outweighed by the danger of unfair prejudice." (quoting *United States v. Hardy*, 643 F.3d 143, 150 (6th Cir. 2011)). The jury is unlikely to understand or to distinguish Cephalon's violation of federal labeling regulations from the conduct alleged here. *See United States v. Johnson*, 27 F.3d 1186, 1193 (6th Cir. 1994) ("When prior acts evidence is introduced, regardless of the stated purpose, the likelihood is very great that the jurors will use the evidence precisely for the purpose it may not be considered . . . ."). There is a very real risk that the jury will assume that because Cephalon pled guilty to marketing-related conduct with no nexus to Ohio, it must be liable now. This is grossly prejudicial. *See State Farm Mut. Auto. Ins. Co. v. Accident Victims Home Health Care Servs.*, Inc., 467 F. App'x 368, 373 (6th Cir. 2012) (reversing judgment and remanding for new trial because "admission of . . . propensity evidence . . . created prejudice to defendants"). For this very reason, the Oklahoma trial court excluded the Plea in the Oklahoma AG action brought against the Moving Defendants and other manufacturers. *See* May 9, 2019, Hearing Transcript, at 157-12-17; 161:2-25; 165:2-3, *State of Oklahoma v. Purdue Pharma, et al*., Case No. CJ-2017-816 (the "Oklahoma Action"), attached as Ex. 2. This Court should do the same.

Finally, Plaintiffs may argue that the Plea establishes that Cephalon admitted to engaging in the off-label promotion of Actiq from January, 2001 to October 1, 2001. However, the introduction of the Plea and conviction is not necessary to the introduction of the admission. That can be established through Cephalon's admission alone. The Plea and conviction simply unnecessarily piles the irrelevant prejudice of criminality on top of an undisputed prior admission. In any event, as explained below, that admission is itself irrelevant to the issues in this case.

B. The Court Should Exclude Reference To "Off-Label" Promotion (TAD-2).

Plaintiffs intend to argue that Moving Defendants' conduct constituted prohibited off-label promotion. (Opp., at 14.) The Court should also exclude, as irrelevant, reference to alleged off-label promotion—that is, any contention that Cephalon or Teva USA promoted Actiq or Fentora in a manner that violated legal restrictions on off-label promotion.[3] That merely interjects a complex set of FDA requirements and guidance, riddled with exceptions and carve-outs, that has nothing to do with what is at issue here, but carries with it the grave risk of sucking the jury down an irrelevant rabbit hole of confusion and side issues.

Whether its conduct constituted off-label promotion has nothing to do with whether Teva USA or Cephalon promoted their opioid products in a false or misleading manner. On the contrary, it is well-settled that off-label promotion is not inherently "false or misleading." *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 552 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3rd Cir. 2015). As a result, any argument or evidence that Cephalon, Teva USA, or any other Moving Defendant's conduct constituted unlawful off-label promotion is irrelevant to Plaintiffs' false marketing and other claims.

By way of example, Plaintiffs' expert, Dr. Kessler, opines that Cephalon engaged in off-label promotion. However, unlike his opinions as to other Defendants, he does not opine that Cephalon engaged in any false marketing. *Compare* D. Kessler Report, ¶¶ 466-82 (Actiq), ECF

[3] In exercising their independent medical judgment, doctors are free to prescribe a medicine—including Actiq or Fentora—to treat any condition or symptom, regardless of whether the condition or symptom is covered by the FDA-approved labeling. *See Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *7 (E.D. Pa. May 21, 2014) ("We stress that it is not illegal for physicians, exercising their independent medical judgment, to prescribe Fentora for off-label use, that is, to patients outside of the breakthrough cancer pain context").

No. 2000-8; *id.*, ¶¶ 483-93 (Fentora), ¶¶ 34-36, p 316 (off-label promotion) *with* ¶¶ 5, 17, 39, 42, p 315-319 (other manufacturers "falsely marketed" other medicines). Because off-label promotion is not inherently fraudulent, his testimony that Cephalon allegedly engaged in unlawful off-label marketing is not relevant and should be excluded.

Such evidence also should be excluded as unfairly prejudicial under Rule 403. A jury may not understand the legal rule that off-label promotion is different from fraud. Plaintiffs must prove that what Cephalon and the other Moving Defendants said to doctors in the Counties was fraudulent. Summit TAC, ¶¶ 169-71; Opp., at 13-15. Dr. Kessler's testimony about off-label promotion will do no such thing; it will only serve to mislead the jury, confuse the matters at issue, and unfairly prejudice Moving Defendants.

Adding to the confusion, the rules around off-label promotion are arcane at best, and founded largely on FDA guidance and publications, and cabined by constitutional restrictions. *See Washington Legal Found. v. Henney*, 202 F.3d 331, 333, 335 (D.C. Cir. 2000) ("action asserting that the policies articulated in [three FDA guidance documents regulating off-label promotion] violated the First Amendment" presented "a difficult constitutional question"). Truthful off-label promotion is also protected by the First Amendment. *Caronia*, 703 F.3d at 169; *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011). Further, even absent First Amendment considerations, the FDA permits a variety of off-label communications by pharmaceutical companies. For example, companies may provide doctors with peer reviewed article reprints on off-label uses. 21 C.F.R. § 99.101(a)(2). They may respond to unsolicited questions from physicians about off-label uses. *Caronia*, 703 F.3d at 156 n.5. They may support medical education which may address off-label uses. *Id.* at 167. To get the jury bogged down in assessing

whether Defendants' conduct constituted off-label activity is to force the jury into an irrelevant, confusing and highly prejudicial mini-trial.

Accordingly, any testimony, evidence, and argument that Cephalon, Teva USA, or any of the other Moving Defendants engaged in off-label promotion should be excluded.

C. The Court Should Exclude Any Reference To The 2008 Civil Settlement Between Cephalon And The Federal Government (TAD-3).

Plaintiffs have made repeated references to a settlement that Cephalon entered into with the Department of Justice in 2008 for claims of off-label marketing (the "Cephalon Settlement"). *See* Summit TAC ¶ 787; Opp., at 10. There was no admission of liability. *See* Cephalon Settlement, attached as Ex. 3, at II.L. Evidence of that settlement, along with any other civil settlements,[4] must be excluded for two separate and independent reasons.

First, Rule 408 precludes introduction of settlement agreements "to prove or disprove the validity or amount of a disputed claim." Fed. R. Evid. 408; *see also Korn, Womack, Stern & Assocs., Inc. v. Fireman's Fund Ins. Co.*, 27 F.3d 566, 1994 WL 264263, at *6 (6th Cir. June 15, 1994) (evidence tending to show acceptance of valuable consideration in compromise of a disputed claim "is inadmissible if it is offered to show the invalidity of the plaintiff's claim or the liability of the defendant."). By the plain language of Federal Rule of Evidence 408(a), evidence of the Cephalon Settlement is inadmissible to show liability, because that settlement involved paying "consideration in compromising . . . the claim[s]" against it. Fed. R. Evid. 408(a)(1); *see also United States v. Robinson*, No. 5:11CR00584, 2012 WL 5386037, at *3 (N.D. Ohio Nov. 2, 2012)

[4] This includes the settlement that the Moving Defendants entered into with the Oklahoma AG in connection with the Oklahoma Action (the "Oklahoma Settlement"). That Oklahoma Settlement is also barred by Rule 408, Rule 402, and Rule 403.

(applying Rule 408 to exclude evidence of settlement); *Day v. NLO, Inc.*, 798 F. Supp. 1322, 1330 (S.D. Ohio 1992) ("Rule 408 bars evidence of both settlement and settlement negotiations.").

Recognizing the critical purpose of promoting settlements, the Sixth Circuit has explained that "[i]t would be unreasonable to expect a party to ever make a settlement offer if doing so forced it into choosing between conceding one or more elements of liability or damages or having the offer admitted against it." *Stockman v. Oakcrest Dental Ctr., P.C.*, 480 F.3d 791, 798–99 (6th Cir. 2007). If Plaintiffs had their way, however, the Cephalon Settlement (and any other settlement agreement involving the Moving Defendants), would become fodder for liability determinations in this trial, thus removing the cloak of protection that attaches to settlements in order to promote the efficient resolution of disputes.

Second, the Cephalon Settlement is irrelevant. The Cephalon Settlement resolved civil claims (pertaining to alleged off-label promotion) based upon different allegations, legal theories, and time periods than are at issue in this case. It did not have anything to do with conduct specific to Summit or Cuyahoga County. Moreover, there was no admission of liability. Thus, the Cephalon Settlement is not relevant to any determination to be made by the jury. *See Bridgeport Music, Inc. v. Justin Combs Pub.*, 507 F.3d 470, 480 (6th Cir. 2007) (quoting *Urseth v. City of Dayton*, 680 F. Supp. 1084, 1098 (S.D. Ohio 1987) ("[A] settlement offer or the fact of settlement negotiations is not direct evidence regarding the factual issues in a case.").); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.*, No. 09-3418 MLC, 2009 WL 3245485, at *4 (D.N.J. Oct. 7, 2009) (dismissing false marketing claims against pharmaceutical manufacturer of opioid medicines notwithstanding allegation that manufacturer previously entered into settlement).

Lastly, even if the evidence of the Cephalon Settlement were otherwise admissible (and it is not), the evidence should be excluded under Fed. R. Evid. 403. *See Stockman*, 480 F.3d at 799

(holding settlement evidence inadmissible under Rule 403 in addition to Rule 408); *see also Goodyear*, 332 F.3d at 982–83 ("the statement [made in furtherance of settlement] would likely be inadmissible under Rules 403 and 408"). Rule 403 permits the Court to exclude even "relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury . . . ." Fed. R. Evid. 403.

That is precisely the case here. If evidence of the Cephalon Settlement were admitted, the jury is likely to conclude—wrongly—that Cephalon acted improperly because it paid significant sums of money to resolve civil actions regarding marketing practices, without ever determining whether the plaintiffs proved their ***specific*** claims ***in this case***. This unwarranted conclusion also may be extended to the other Moving Defendants by affiliation. Indeed, a jury may believe—wrongly—that if Cephalon did nothing wrong, it would not have settled. This risk of unfair prejudice is "profound." *See United States v. Hays*, 872 F.2d 582, 589 (5th Cir. 1989) ("[T]he potential impact of evidence regarding a settlement agreement with regard to a determination of liability is profound. It does not tax the imagination to envision the juror who retires to deliberate with the notion that if the defendants had done nothing wrong, they would not have paid the money back."), *cited with approval in Stockman*, 480 F.3d at 800. The Cephalon Settlement (as well as the Oklahoma Settlement) should be excluded.

D. The Court Should Exclude Evidence Of Opioid-Related Harm That Occurred Outside Of The Counties (TAD-4).

This Court should prohibit any evidence regarding any harm that occurred outside of Ohio. As a matter of law, the Counties can only recover for any harm that ***they*** incurred.[5] As a result,

[5] 18 U.S.C. § 1962(c) (under RICO, plaintiff must be injured "in his business or property"); Ohio Rev. Code Ann. § 2923.34 (OCPA limits standing to "person who is injured"); *Lawyers Title Co., LLC v. Kingdom Title Sols., Inc.*, 592 F. App'x 345, 355 (6th Cir. 2014) ("if a plaintiff suffers no actual damages

any opioid-related harm experienced by other counties in Ohio, or that occurred elsewhere in the United States, is entirely irrelevant. For instance, Plaintiffs seek to utilize expert testimony and documents relating to opioid-related harms, including studies and instances of opioid-related addiction, outside of the Counties. *See*, *e.g.*, Mark Schumacher Expert Report ¶¶ 53-56, ECF No. 2000-24 (discussing studies about a "national" epidemic but none that examine the Counties); Anna Lembke Expert Report, at 81-85, ECF No. 2000-10 (citing national studies and studies on opioid abuse in "Los Angeles . . . San Diego, Seattle, and New York" but none examining the Counties). But that says nothing about any harm that has occurred in the Counties. To the extent Plaintiffs seek to introduce such evidence, it should be precluded as irrelevant under Rule 402.

Moreover, even if such evidence were relevant, it is unduly prejudicial and Rule 403 precludes its admission. The case is brought by two Counties in Ohio, based upon alleged false marketing made to doctors in the Counties and alleged excessive shipments of opioids into the Counties. If the jury is allowed to hear testimony about opioid-related harm in other parts of the United States, it will unduly influence its decision-making. Jurors may wrongly believe that because other areas of the country have experienced significant opioid-related harm, so must have Summit and Cuyahoga, without the Counties having to prove their legally cognizable injuries and damages. The prejudice clearly outweighs the risk.

E. The Court Should Exclude Evidence Of Marketing-Related Statements Or Opioid Shipments Outside Of The Counties (TAD-5).

Plaintiffs' false marketing claims rest upon the theory that the Teva and Actavis Generic Defendants misled doctors in the Counties into writing prescriptions that were harmful to residents

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from the underlying unlawful act, there can be no successful civil conspiracy action") (citation and quotation omitted); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 480 (6th Cir. 2017) (common law public nuisance claim requires injury to plaintiff).

of the Counties. *See Summit* TAC, ¶¶ 10-11, 15, 71, 674-79, 715, 722. As a result, evidence of marketing activity, either branded or unbranded, should be excluded where there is no showing that the marketing materials were distributed, published, or read in either County. For example, Plaintiffs seek to use a "Pain Matters" program sponsored by Teva USA in support of their claims (Opp., at 14-15), but there is no evidence that this program was viewed by any doctor, patient, or person in Cuyahoga or Summit County. Nor have any of Plaintiffs' causation experts even considered it. Thus, even if certain statements in that video were false, they have no relevance to the claims brought by Plaintiffs. Fed. R. Evid. 402. At a minimum, any such relevance is substantially outweighed by the prejudice of allowing marketing statements with no nexus to the Counties. Fed. R. Evid. 403.

Likewise, as explained in greater detail in the Joint Brief, any evidence of shipments of opioids manufactured or sold by the Teva or Actavis Generic Defendants should be excluded where those shipments have no connection to Ohio. For instance, Plaintiffs have argued that Teva USA purportedly released a suspicious order placed by a Publix store in Florida. (Opp., at 18). Putting aside that Plaintiffs are wrong, this order has no connection to the Counties; it was never shipped into the Counties, thus, it has no bearing on any of the claims brought by Plaintiffs for harm in the Counties. *See Worldwide Basketball & Sports Tours, Inc. v. Nat'l Collegiate Athletic Ass'n*, No. 2:00-CV-1439, 2003 WL 21750835, at *5 (S.D. Ohio July 11, 2003) (excluding evidence relating to non-party that suffered harm). It is entirely irrelevant.[6]

In fact, allowing Plaintiffs to base liability on this evidence would be a constitutional violation. Under the Commerce Clause, the Counties cannot project Ohio's regulatory regime into

[6] As explained in the Joint Brief, evidence of opioid shipments outside of the Counties is also inadmissible under Fed. R. Evid. 404(b). *See* Joint Brief at Section II(6).

another state—even if the Counties can point to some downstream effect they want to prevent. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989).[7] This means that the Counties cannot rely upon Moving Defendants' out-of-state conduct to satisfy the elements of Ohio state-law claims; indeed, the Supreme Court has held that the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, *whether or not the commerce has effects within the State*." *Id.* (citations omitted) (emphasis added). Nor can the Counties rely upon out-of-state conduct to try to impose punitive damages (which, as described in the Joint Brief, are unavailable here anyway). *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003). The Counties' attempt to penalize Moving Defendants under Ohio law, based on conduct outside of Ohio, is unconstitutional.[8]

F. The Court Should Exclude Evidence Regarding Teva Defendants' Financial Support Of Third-Party Groups (TAD-6).

Plaintiffs seek to hold Moving Defendants liable for the conduct of trade organizations that they funded, such as the American Pain Foundation. (Opp., at 13-14).[9] But the First Amendment shields Moving Defendants' right to associate with trade and advocacy organizations. U.S. Const. amend. I (protecting "the right of the people peaceably to assemble"). That protection extends across a broad range of activities, including funding: "The freedom to associate with others for the dissemination of ideas—not just by singing or speaking in unison, but by pooling financial

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[7] *See also Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935); *Edgar v. MITE Corp.*, 457 U.S. 624, 641 (1982); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986).

[8] Likewise, the Supreme Court has made clear that the application of state law to out-of-state conduct violates the Due Process Clause unless the out-of-state conduct has significant contacts with the state and implicates significant state interests. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821-22 (1985). Here, the Counties cannot meet their burden to establish that that Moving Defendants' marketing conduct outside of Ohio has any pertinent contact with Ohio or implicates any state interest, much less a significant one.

[9] *See, e.g.*, Summit TAC, ¶¶ 360-71 (seeking to hold Defendants responsible for statements made by the American Academy of Pain Medicine and the American Pain Society in their consensus statements about and guidelines for the use of opioids).

resources for expressive purposes—is part of the freedom of speech." *McConnell v Fed. Election Comm'n*, 540 U.S. 93, 255 (2003) (overruled on other grounds by *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310 (2010)). And it applies equally to all types of advocacy. *NAACP v. Ala. ex rel. Patterson*, 357 U.S. 449, 460-61 (1958). As a matter of law, "[j]oining organizations that participate in public debate, making contributions to them, and attending their meetings are activities that enjoy substantial First Amendment protection." *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1294 (3d Cir. 1994). Because funding third-party trade groups is protected First Amendment activity, Plaintiffs should be precluded from offering evidence about contributions by the Moving Defendants to such third-party groups—or any argument that the Moving Defendants are liable based upon such contributions.

In addition, Plaintiffs should be precluded from arguing that Cephalon, Teva USA, and the other Moving Defendants are responsible for statements made by such third-party groups. To establish liability against the Moving Defendants for statements made by third-party groups, Plaintiffs must show that the third party served as an agent of the Moving Defendants or was part of some conspiracy or RICO enterprise involving the Moving Defendants. But Plaintiffs have not made any such showing.[10] They have taken no discovery of any third-party trade or advocacy groups; thus, they have no testimony or documents from those groups. Nor is there a shred of evidence that the Teva Defendants controlled any such groups, much less that any such groups were aware of and agreed to participate in some unlawful scheme. *See Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416-17 (S.D. Ohio. 1986) ("central factor under Ohio law in determining whether an agency relationship exists is the right of control vested in the principal."). While

[10] Nor have Plaintiffs shown that any statements made by third-party groups caused any prescriber to inappropriately prescribe Moving Defendants' opioid medications in the Counties.

Cephalon and Teva USA participated in and funded certain groups, that is protected First Amendment conduct and, as a matter of law, it is insufficient to hold the Teva Defendants' liable for their statements.[11] As a result, the Court should exclude any argument that the Teva Defendants are liable for any group's publications, programs, or other conduct. At a minimum, Plaintiffs should have to make an evidentiary proffer—outside of the jury—before making such an argument.

G. The Court Should Exclude Testimony From Russell Portenoy About Any Improper Conduct By Moving Defendants (TAD-7).

The Court should exclude any testimony from Russell Portenoy ("Portenoy") at trial about any supposedly improper conduct by Moving Defendants, because he has already testified that he has no evidence of any such wrongdoing by them. *See* Fed. R. Evid. 402. Moreover, because he cannot identify any wrongdoing by the Moving Defendants, any probative value of Portenoy's testimony about "manufacturer defendants" in general is substantially outweighed by the danger of unfair prejudice and confusion to the Moving Defendants. Fed. R. Evid. 403.

As part of a settlement agreement with Plaintiffs to have claims against him dismissed, Portenoy agreed to cooperate with and assist them. Portenoy Decl., attached as Ex. 4, ¶ 3. Part of this cooperation included a written declaration that makes general statements about "drug companies" and "drug manufacturers," including that they supposedly overstated the benefits of chronic opioid therapy, understated the risks, and misused his work "by referencing the positive

[11] *See, e.g., Gen. Bldg. Contractors Ass'n v. Pennsylvania*, 458 U.S. 375, 395 (1982) (sponsorship or funding is insufficient as a matter of law to attribute a third party's statement to a defendant); *Almanza v. United Airlines, Inc.*, 851 F.3d 1060, 1072 (11th Cir. 2017) (participation in trade association cannot establish a RICO conspiracy or enterprise); *In McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008) (defendant not liable for third-party statements because no evidence that third party acted as defendant's agent with respect to the challenged statements); *In re Welding Fume Prods. Liab. Litig.*, 526 F. Supp. 2d 775, 804-06 (N.D. Ohio 2007) (attendance at trade group meetings, even if defendant knew of supposedly improper scheme, was insufficient to hold defendant liable).

statements that I made repeatedly without providing the background, analysis of the literature, and cautions that accompanied these positive statements." *Id*. ¶¶ 34, 45, 49.

Portenoy, however, has already conceded under oath—during a deposition in the Oklahoma AG litigation—that none of the statements in his declaration apply to Moving Defendants. For instance, he never had any communications with, nor was aware of any marketing conducted by or funding he received from, any of the Actavis Generic Defendants or Teva USA. *See* Portenoy January 24, 2019, Deposition Transcript in *State of Oklahoma v. Purdue Pharma, et al.*, Case No. CJ-2017-816, at 459:12-2; 460:8-462:10; 472:13-473:7, ECF No. 1969-11. In addition, Portenoy testified "there was nothing false or misleading" in any programs funded by Cephalon and "never any effort on the part of [the] company . . . to change my messages or ask me to use specific slides." *Id*. at 463:20- 466:3; 466:20-467:6; 468:1-471:12. He could not identify a single instance in which Cephalon or Teva USA "referenc[ed] the positive statements that [he] made repeatedly without providing the background, analysis of the literature, and cautions that accompanied these positive statements." *Id*. at 474:24-475:16; 476:19-25; 477:25-478:6. In short, Portenoy could not identify a single instance during his deposition in which any of the Moving Defendants engaged in any of the conduct described in his declaration.[12] As a result, Portenoy's generalized statements about "drug companies" and "drug manufacturers" would only further confuse the jury since those statements improperly lump the Moving Defendants (whom Portenoy concedes did nothing wrong) with all the other defendants. Portenoy should be precluded from testifying about any alleged misconduct by the Moving Defendants.

[12] *Id*. at 480:19-481:9; 483:1-22; 484:3-486:20; 488:14-490:8; 490:14-492:6; 492:19-493:4; 494:12-16.

H. Plaintiffs Should Be Precluded From Arguing That The Actavis Generic Defendants Should Have Made Additional Warnings Regarding Their Generic Medicines Or Should Have Stopped Selling Them (TAD-8).

This Court has recognized that the "sameness" requirement under Food Drug & Cosmetic Act prohibits manufacturers of generic medicines from providing warnings or communications beyond those provided in their generic labels—which must be the same as those of their branded equivalents. *See* Op. & Order Denying Defs.' Mot. Summ. J., at 10, ECF No. 2565. As a logical consequence of the principle, the Court held that "to the extent that the state law claims depend upon . . . allegations [that Generic Manufacturers should have sent warnings that the Brand-Name Manufacturers had not sent] . . . they are preempted because it would be impossible for Generic Manufacturers to comply with both federal law and the supposed state law duty.'" *Id.* (alterations added) (quoting *Muscogee* R. & R., at 42, ECF No. 1499). Because evidence that the Actavis Generic Defendants should have sent additional warnings or communications relates only to Plaintiffs' preempted legal theory, any evidence, testimony, or argument relating to that theory is irrelevant and should be precluded. *See Rheinfrank v. Abbott Labs.*, Inc., No. 1:13-CV-144, 2015 WL 5258858, at *2 (S.D. Ohio Sept. 10, 2015) (excluding evidence that drug manufacturer defendant should have strengthened product's warning labelling because the theory is preempted).

Likewise, the Court should exclude any evidence or argument suggesting that Generic Manufacturers (or any other Moving Defendant) should have refrained from selling FDA-approved drugs altogether, unless they corrected alleged misimpressions by others about opioids. Both the Supreme Court and the Sixth Circuit have both rejected this "stop-selling" theory of

avoiding liability.[13] Because this legal theory is untenable, any evidence or argument referencing the theory should be excluded.

I. The Court Should Exclude Reference To The Purchase Price Paid By Teva Pharmaceutical Industries Ltd. For The Actavis Generic Defendants (TAD-9).

Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") purchased the generics business from Allergan PLC ("Allergan"), including the Actavis Generic Defendants, in August 2016. The purchase price ($40.5 billion) should be excluded for both lack of relevance and prejudice.

First, even if the acquisition were relevant, the ***amount*** of the purchase price for the acquisition of the Actavis Generic Defendants is certainly not. *See Brooks v. Caterpillar Glob. Mining Am., LLC*, No. 4:14CV-00022-JHM, 2017 WL 3401476, at *13 (W.D. Ky. Aug. 8, 2017) (excluding evidence of "the financial condition or net worth of [defendant] and the purchase price of [acquired company because they] are not relevant to the [plaintiff's] claim."). It has no connection to any liability-related issue. Any such evidence should be excluded under Rule 402.[14]

Second, even if this Court were to find the purchase price paid by Teva Ltd. relevant, its probative value, if any, is substantially outweighed by the danger of confusing the jury and unfair prejudice to the Moving Defendants. This evidence would mislead the jury into making incorrect

[13] *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013) ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence."); *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 925 (6th Cir. 2014) (rejecting theory that "a generic manufacturer could have avoided the conflict between state and federal law by refraining from selling the drug").

[14] Teva Ltd. maintains that Plaintiffs have failed to show that personal jurisdiction exists over Teva Ltd. *See* Op. & Order regarding Mot. Dismiss, at 8-9, ECF No. 2131.

assumptions about the current financial health of Teva Ltd. and its subsidiaries. It may even cause the jury to impose liability merely because of a misguided notion that the Moving Defendants "can afford it." For this reason, the Sixth Circuit has made clear that statements relating to "the wealth . . . of one of the parties 'are clearly calculated to direct the jury's attention to . . . compensation rather than the real issues in the case' and have been held to be prejudicial error." *City of Cleveland v. Peter Kiewit Sons' Co.*, 624 F.2d 749, 756-57 (6th Cir. 1980) (holding such evidence warrants exclusion where counsel "sought to plant the seed in the minds of the jurors that [defendant] was a very large corporation with international operations.") (citation and quotation omitted).

J. The Court Should Exclude Reference To The Settlement Agreement Between Teva Ltd. And Allergan (TAD-10).

Following Teva Ltd.'s purchase of the generic business from Allergan, Teva Ltd. and Allergan entered into a separate agreement ("Settlement Agreement", ECF No. 1909-4). *See* Pls.' Opp'n. Allergan Mot. Summ. J. ("Pls.' Opp. Allergan"), ECF No. 2219, at 7. Plaintiffs have referenced the Settlement Agreement in their briefing. *See* Pls.' Opp'n. Teva Ltd. Mot. Dismiss, ECF No. 1815, at 20. This Settlement Agreement—which Plaintiffs call an indemnification arrangement—has no bearing on Plaintiffs' claims, as it would not make any fact for the jury's consideration "more or less probable than it would be without the evidence."[15] Fed. R. Evid. 401. For that reason, courts generally do not allow evidence of indemnification agreements before the jury. *See, e.g.*, *Larez v. Holcomb*, 16 F.3d 1513, 1518–19 (9th Cir. 1994); *Jean–Laurent v.*

[15] Plaintiffs themselves have disclaimed any potential relevance of the Settlement Agreement by conceding that an adjudication of Allergan's rights under the Settlement Agreement vis-à-vis Teva Ltd. is not before this Court—asserting that "[w]hether Teva has assumed liability for the transferred entities is subject to likely dispute between Teva and Allergan." (Pls.' Opp. Allergan, at 19).

Hennessy, 840 F. Supp. 2d 529, 550 (E.D.N.Y. 2011). The same result should apply here, too. Such evidence should be excluded under Rule 402.

CONCLUSION

For the foregoing reasons, the Moving Defendants ask that the Court grant this motion and instruct Plaintiffs and all counsel not to mention, refer to, interrogate about, or attempt to convey in any manner, either directly or indirectly, any of these matters. Moving Defendants further reserve the right to supplement this Motion prior to trial, particularly because certain documents, such as the settlement agreement between Allergan and Plaintiffs, have not yet been provided and Plaintiffs have not yet provided a manageable list of witnesses or documents.

Dated: September 25, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on September 25, 2019, the Teva Defendants' and Actavis Generic Defendants' General Motion in Limine, along with supporting exhibits, was served via email on all attorneys of record consistent with the June 24, 2019 Order setting forth Directions Regarding Filing of Briefs Under Seal.

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